510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

JUN 29 2007

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Proprietary Name:	GORE Balloon Sheath and Dilator
Common Name:	Occlusion Balloon
Classification Name:	Catheter, Intravascular Occluding, Temporary
Device Classification:	Class II
Product Classification and Code:	870.4450, MJN
Classification Panel:	General and Plastic Surgery
Establishment Registration Number:	2017233
Contact Person:	Timothy Rynn Regulatory Affairs Medical Products Division W. L. Gore & Associates, Inc. 3450 West Kiltie Lane Flagstaff, AZ 86002-0500 Telephone: (928) 864-3714 Facsimile: (928) 864-2735 E-mail: trynn@*wlgore.com*

Indications for Use:

The GORE Balloon Sheath is indicated for temporary occlusion, selective angiography, and/or facilitating the introduction and placement of intravascular devices into selected blood vessels in the peripheral and neurovascular systems.

Device Description:

The GORE Balloon Sheath consists of a dual lumen catheter shaft with a compliant balloon mounted at the distal-most tip of the shaft. The GORE Balloon Sheath is provided with compatible dilator which facilitates a gradual transition from the guide wire diameter to the sheath internal diameter. The first lumen acts as the inflation lumen while the second lumen acts as the working channel, accommodating diagnostic and therapeutic interventional devices. The sheath hub consists of four ports. The first port ("balloon inflation port") has a female luer thread, allowing assembly of a syringe and stopcock for balloon inflation.

The second port ("fluid port") has a flexible tubing extension, which permits access to the working channel to subsequently allows fluid (e.g. contrast agent) injections and / or blood aspiration.

The third port ("auxiliary port") allows side access to the working channel to introduce interventional devices.

The fourth port ("main port") provides linear access to the working channel, functioning primarily as the delivery port for diagnostic and therapeutic devices.

Testing:

Biocompatibility of the GORE Balloon Sheath and Dilator were verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices. Testing confirmed the biocompatibility of the GORE Balloon Sheath as an external communicating blood contact short duration (<24 hours) device.

Performance testing was conducted in accordance with ISO 10555 Sterile, single use intravascular catheter, Part 1. Tests included biocompatibility, dimensional verification, force to break, freedom from leakage, and balloon integrity. Testing demonstrates that the device meets or exceeds the requirements of the standard and performs substantially equivalent to the predicate devices.

Predicate Devices:

- ArteriA Medical ParCA Catheter K001917
- ArteriA Medical Occlusion Balloon K002286
- Concentric, Concentric Guide Catheter K003085

Summary of Substantial Equivalence:

The GORE Balloon Sheath and Dilator are substantially equivalent to the predicate devices in technological characteristics and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2007

W.L. Gore & Associates
c/o Mr. Alan Curtis
AEC Consulting
2647 Lin Gate Court
Pleasanton, CA 94566

Re: K070770
GORE Balloon Sheath
Regulation Number: 21 CFR 870.4450
Regulation Name: Catheter, Intravascular Occluding, Temporary
Regulatory Class: Class II
Product Code: MJN
Dated: May 5, 2007
Received: May 6, 2007

Dear Mr. Curtis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K070770

Device Name: GORE BALLOON SHEATH

Intended Use / Indication For Use: The GORE Balloon Sheath is indicated for temporary occlusion, selective angiography, and/or facilitating the introduction and placement of intravascular devices into selected blood vessels in the peripheral and neurovascular systems.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use	X	OR	Over-The-Counter Use
(Per 21 CFR 801.109)			(Optional Format 1-2-9-96)

Susan R. Mitchell

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K070770